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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
WOOD, AMANDA P	

ART UNIT	PAPER NUMBER
1657	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,985	KARLSSON ET AL.	
	Examiner	Art Unit	
	AMANDA P. WOOD	1657	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) *5-15 and 17-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Invention I (claims 1-11 and 16) and of the species detecting eosinophil shape change using flow cytometry in the reply filed on 18 July 2008 is acknowledged. The traversal is on the ground(s) that the inventions do not lack unity because the references cited by the Examiner fail to teach or suggest the invention as a whole. This is not found persuasive because the common unifying feature among the Inventions is assaying for histamine H4 receptor-mediated effect using histamine H4 antagonists and agonists, and this feature is taught by Gantner et al, as cited previously by the Examiner, as well as by Jenkinson et al, as cited by Applicant in the IDS filed on 18 July 2008, and by Cai et al in US 7,226,938.

The requirement is still deemed proper and is therefore made FINAL.

Claims 5-15 and 17-24 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and/or species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 18 July 2008.

Claims 1-4 and 16 are presented for consideration on the merits.

Priority

Applicant's claim to priority of PCT/US04/31614 filed on 24 September 2004 and of US Provisional application 60/506434 filed on 26 September 2003 has been considered.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 18 July 2008 has been considered by the examiner, and a signed copy is included with this Office Action.

Drawings

The drawings filed on 21 March 2006 have been received and accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, Applicant recites the phrase "treating whole blood from a source" in line 4 of claim 1. It is unclear from what type of source Applicant wishes to encompass in the claims, as drafted (e.g., is only human blood to be used or can blood from other mammals or living animals be used, is the source blood from a blood bank or possibly a pooled source of blood).

All other claims depend directly or indirectly from rejected claims and are, therefore, also rejected under USC 112, second paragraph for the reasons set forth above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jenkinson et al (WO 02/056871 A2), as cited in the IDS filed on 18 July 2008, in view of Cai et al (US 7,226,938 B2).

A method is claimed for assaying histamine H4 receptor-mediated effect.

Jenkinson et al beneficially teach a functional assay method for determining the ability of histamine to induce chemotaxis in eosinophils isolated from human blood. In particular, Jenkinson et al utilize antagonists and agonists of histamine H4 receptor in the above method to show that histamine-induced chemotaxis of human eosinophils appears to be mediated by the histamine H4 receptor and not by the histamine H3 receptor (see, for example, page 8, lines 8-23 of Jenkinson et al).

Jenkinson et al do not expressly teach a method of detecting eosinophil shape change.

Cai et al beneficially teach that the change in shape of eosinophils is due to cytoskeletal changes tha tproceed chemotaxis and is thus a measure of chemotaxis. Furthermore, Cai et al beneficially teach a method wherein human granulocytes were harvested from human blood and the red blood cells lysed, and the granulocytes washed with FACS buffer then incubated with test compound solutions comprising

specific histamine receptor antagonists (e.g., antagonists for H1, H2, H3/H4 and H4). Jenkinson et al beneficially teach that the eosinophil shape change was quantitated using a gated autofluorescence forward scatter assay (GAFS). Cai et al determined that antagonists for H1 and H2 receptors did not alter histamine-induced eosinophil shape change, whereas a dual H3/H4 antagonist and a specific histamine H4 receptor antagonist inhibited histamine-induced eosinophil shape change (see, for example, col. 27, lines 1-55).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the methods disclosed by Jenkinson et al based upon the beneficial teachings provided by Cai et al, with respect to well-known method of detecting eosinophil shape change, which precedes eosinophil chemotaxis, using a gated autofluorescence forward scatter assay, as discussed above. The result-effective adjustment of particular conventional working conditions (e.g., using a whole blood sample as opposed to using a sample of granulocytes or eosinophils isolated from whole blood, and/or using a particular method for determining eosinophil shape change) is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole, was *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made, as evidenced by the cited references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AMANDA P. WOOD whose telephone number is (571)272-8141. The examiner can normally be reached on M-F 8:30AM -5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber can be reached on (571) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

APW
Examiner
AU 1657

/Lisa J. Hobbs/
Primary Examiner, Art Unit 1657